

1 Andy D. Birchfield, Jr. (BIR006)
2 Navan Ward, Jr. (WAR062)
3 BEASLEY, ALLEN, CROW, METHVIN,
4 PORTIS & MILES, P.C.
5 Post Office Box 4160
6 Montgomery, Alabama 36103-4160
(334) 269-2343 telephone
(334) 954-7555 facsimile

7 Attorneys for Plaintiff

8 IN THE UNITED STATES DISTRICT COURT
9 FOR THE NORTHERN DISTRICT OF CALIFORNIA
10 (SAN FRANCISCO DIVISION)

11 IN RE: BEXTRA AND CELEBREX
12 MARKETING SALES PRACTICES AND
13 PRODUCT LIABILITY LITIGATION

MDL No. 1699

14 BETTY DAVIS-BARBOSA (MN), MARY
15 JEANETTE HILL (FL) GARY HOPE (WA),
16 JAMES WILEY (WI), CHARLES
17 STELIMASKEWSKI (FL), MARY SMITH
(MI);

Case No. 07-29

CIVIL COMPLAINT

JURY TRIAL DEMANDED

18 Plaintiffs,

19 v.

20 PFIZER, INC., PHARMACIA
21 CORPORATION, G.D. SEARLE LLC, (FKA
22 G.D. SEARLE & CO.), and MONSANTO
23 COMPANY,

Defendants.

24 Plaintiffs, Betty Davis-Barbosa, Mary Jeanette Hill, Gary Hope, James Wiley, Charles
25 Stelimaskewski and Mary Smith by and through their counsel, bring this action against
26 Defendants PFIZER, INC., PHARMACIA CORP., MONSANTO COMPANY, and G.D.
27 SEARLE LLC. (hereinafter collectively "Defendants") and allege as follows:
28

I. PARTIES

1
2 1. This is an action for damages arising from Defendants' design, manufacture, sale,
3 testing, marketing, advertising, promotion, and/or distribution of the unsafe medication
4 Celecoxib, trade name CELEBREX® ("CELEBREX").

5 2. Plaintiff Betty Davis-Barbosa was at all relevant times adult resident citizen of the
6 State of Minnesota, County of Faribault. Plaintiff was prescribed and began taking CELEBREX
7 for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered
8 severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
9 cardiovascular injury or heart attack on or about December 15, 2003, which has caused and will
10 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

11 3. Plaintiff Mary Jeanette Hill was at all relevant times adult resident citizen of the
12 State of Florida, County of Leon. Plaintiff was prescribed and began taking CELEBREX for the
13 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe
14 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
15 cardiovascular injury or heart attack on or about December 19, 2003, which has caused and will
16 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

17 4. Plaintiff Gary Hope was at all relevant times adult resident citizen of the State of
18 Washington, D.C., County of Washington, D.C. Plaintiff was prescribed and began taking
19 CELEBREX for the treatment of pain. As a direct and proximate result of using CELEBREX,
20 Plaintiff suffered severe cardiovascular injuries while taking CELEBREX, including, but not
21 limited to, serious cardiovascular injury or heart attack on or about December 18, 2004, which
22 has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further
23 serious injury or death.

24 5. Plaintiff James Wiley was at all relevant times adult resident citizen of the State
25 of Wisconsin, County of Racine. Plaintiff was prescribed and began taking CELEBREX for the
26 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe
27 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
28 cardiovascular injury or heart attack on or about December 26, 2004, which has caused and will
continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

1 6. Plaintiff Charles Stelimaskewski was at all relevant times adult resident citizen of
2 the State of Florida, County of Sarasota. Plaintiff was prescribed and began taking CELEBREX
3 for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered
4 severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
5 cardiovascular injury or heart attack on or about December 26, 2003, which has caused and will
6 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death

7 7. Plaintiff Mary Smith was at all relevant times adult resident citizen of the State of
8 Michigan, County of Wakulla. Plaintiff was prescribed and began taking CELEBREX for the
9 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe
10 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious
11 cardiovascular injury or heart attack on or about December 1, 2004, which has caused and will
12 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death

13 8. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place
14 of business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly
15 \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the
16 business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and
17 selling the drug Celecoxib, under the trade name CELEBREX in California and nationwide.

18 9. Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. ("Searle") is
19 a Delaware corporation with its principal place of business in Illinois. At all relevant times,
20 Searle has been engaged in the business of marketing and selling CELEBREX nationwide and in
21 California. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged
22 within this Complaint.

23 10. Defendant Monsanto Company ("Monsanto") was the parent corporation of Searle
24 and is a Delaware corporation. At all times relevant hereto, Monsanto, through its subsidiary
25 companies, was in the business of manufacturing, marketing, selling and distributing the
26 pharmaceutical product CELEBREX nationwide.

27 11. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with
28 its principal place of business in New Jersey. At all relevant times, Pharmacia, and its

1 predecessors in interest have been engaged in the business of designing, testing, manufacturing,
2 packaging, marketing, distributing, promoting, and selling CELEBREX nationwide and in
3 California.

4 **II. JURISDICTION AND VENUE**

5
6 12. This is an action for damages, which exceeds seventy-five thousand dollars
7 (\$75,000.00).

8 13. There is complete diversity of citizenship between the Plaintiffs and Defendants.
9 This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332
10 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there
11 is complete diversity of citizenship between Plaintiffs and Defendants.

12 14. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A.
13 § 1391. Defendants marketed, advertised and distributed the dangerous product in the district,
14 thereby receiving substantial financial benefit and profits the dangerous product in this district,
15 and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

16 15. At all relevant times herein, Defendants were in the business of designing,
17 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and
18 selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed,
19 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce
20 the aforementioned prescription drug. Defendants do substantial business Nationwide and within
21 this Federal Judicial District, advertise in this district, receive substantial compensation and
22 profits from sales of CELEBREX in this District, and made material omissions and
23 misrepresentations and breaches of warranties in this District so as to subject them to *in personam*
24 jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the
agent for each of the other defendants, or those defendant's predecessors in interest.

25 **III. INTERDISTRICT ASSIGNMENT**

26 16. Assignment to the San Francisco Division is proper as this action is related to *In*
27 *Re: Celebrex and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the
28 Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,

2005. (See also, MDL-1699 Pretrial Order No. 2)

IV. FACTUAL BACKGROUND

A. Facts Regarding All Plaintiffs

17. Plaintiffs and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries unaware - and could not have reasonably known or have learned through reasonable diligence - that such injury directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from Plaintiffs' ingestion of CELEBREX.

18. Plaintiffs used CELEBREX in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

19. Plaintiffs would not have used CELEBREX had Defendants properly disclosed the risks associated with the drug.

B. Facts Regarding CELEBREX: Science and other Cox-2 Inhibitors

20. CELEBREX is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs.

21. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

22. In addition to decreasing inflammation, the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

1 19. Prosagalin I2 is the predominant cyclooxygenase product in endothelium,
2 inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing
3 the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A2
4 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected. Thromboxane A2
5 is a potent platelet aggregator and vasoconstrictor which is synthesized by platelets. Therefore,
6 while the older NSAIDS suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors
7 support it.
8

9
10 20. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by
11 inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional
12 NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood
13 clots, rather they actually reduce the risk of clots and help protect heart function.

14 21. Defendants and other pharmaceutical companies set out to remedy these ulcer and
15 bleeding problems suffered by some NSAID users by developing “selective” inhibitors that
16 would block only COX-2 production, thus (supposedly) allowing the proper maintenance of
17 gastric tissue while still reducing inflammation.
18

19 22. In making this decision, Defendants and their predecessors in interest either
20 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2
21 inhibition lowers prostacyclin levels and causes thromboxane A₂ to be uninhibited, causing blood
22 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,
23 unstable angina. The vasoconstriction and fluid retention cause the hypertension.
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1 23. Pfizer launched CELEBREX, the first of the three major COX-2 inhibitor drugs, in
2 January 1999 and initiated a massive marketing campaign to convince doctors and consumers of
3 the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May, 1999,
4 Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.
5

6 24. Seeking increased market share in this extremely lucrative market, Defendants,
7 and their predecessors in interest, also sought approval of a “second generation” selective COX-2
8 inhibitor and filed for FDA approval of Celecoxib (Celebrex) on January 16, 2001 for the
9 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief
10 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.
11

12 **C. Facts Regarding CELEBREX’S Safety and Defendants’ Knowledge Thereof**
13

14 25. The potential for cardiovascular risk of selective COX-2 inhibitors was known to
15 Defendants long before the market launch. By 1997, and prior to the submission of the New
16 Drug Application (the “NDA”) for CELEBREX, Defendants was aware that, by inhibiting COX-
17 2, CELEBREX altered the homeostatic balance between prostacyclin synthesis and thromboxane
18 and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those
19 who ingested it. *See* Topol, E.J., *et al.*, *Risk of Cardiovascular Events Associated with Selective*
20 *Cox-2 Inhibitors*, *JAMA*, August 22, 2001 at 954.
21

22 26. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania,
23 reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004,
24 that it was known as early as 1999 that selective COX-2 inhibitors, such as CELEBREX,
25 suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation
26 in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.
27
28

1 27. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and
2 basic research on this type of selective inhibitor which had been widely conducted, Defendants
3 knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed
4 serious cardiovascular risks for anyone who took them, and presented a specific additional threat
5 to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective
6 COX-2 inhibitors, including CELEBREX, decrease blood levels of a prostacyclin. When those
7 levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and
8 stroke.
9

10
11 28. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing
12 new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action
13 to protect the health and welfare of patients, but instead, continued to promote the drug for sale
14 even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug
15 Advisory Committee meetings.
16

17 **1. CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

18 29. The defendants touted the CELEBREX Long-Term Arthritis Safety Study
19 ("CLASS") as the primary evidence to support its theory that CELEBREX was safer for
20 consumers that could not tolerate traditional NSAIDs in their gastrointestinal system. (CLASS
21 data is found in NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000.
22 CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D.
23 (FDA Medical Officer) on September 20, 2000.)
24

25 **2. CLASS**

26 30. The FDA Medical Officer Review of the CLASS data proves CELEBREX is no
27 more efficacious than other traditional NSAIDS and is harmful to consumers. See generally,
28

1 FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by G.D. Searle on
2 June 12, 2000 ("FDA CLASS Review"). On April 7, 2005, the FDA issued an *Alert* noting only
3 minimal information is available regarding CELEBREX: "The only available data from a long
4 term comparison of CELEBREX to other NSAIDs came from the CLASS study...."

5
6 31. Pfizer misrepresented the data in CLASS by using biased authors. According to
7 the *Washington Post* the CLASS authors were either employees of Pharmacia, CELEBREX'S
8 manufacturer, or paid consultants of the company. Pfizer needed a study to demonstrate that its
9 Cox-2 inhibitor was safer for the stomach than older cheaper medications: CLASS was designed
10 to be that study. Unfortunately, the results of the completed study revealed the truth –
11 CELEBREX offered no gastrointestinal (GI) benefit. Instead of releasing the complete –12-
12 month – results from CLASS, Pfizer had only the first six months of data published in the *Journal*
13 *of American Medicine*. JAMA 2000,48:1455-1460.
14

15
16 32. "After reviewing the full study, the FDA's arthritis advisory committee concluded
17 that CELEBREX offers no proven safety advantage over the two older drugs in reducing the risk
18 of ulcer complications, said FDA spokesman Susan Cruzan." *Washington Post*, August 5, 2001.
19 According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any
20 statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with
21 regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal
22 Adverse Events) at any point in the trial although there were trends that favored celecoxib" (FDA
23 CLASS Review)

24 33. According to an August 5, 2001 article in the *Washington Post*, editors of the
25 *Journal of the American Medical Association* (JAMA) and other medical experts, "were
26 flabbergasted" when they realized they had been duped by only being provided with the first six
27 months of CLASS data. The *Washington Post* reported JAMA editors as saying: "When all of the
28 data were considered, most of CELEBREX'S apparent safety advantage disappeared."

1 34. The “scientific double-cross” boosted sales. “[T]he JAMA article and editorial
2 have likely contributed to CELEBREX’S huge sales. ‘When the JAMA article comes out and
3 confirms the hype, that probably has more impact than our labeling does,’ said Robert J. Temple,
4 director of medical policy at the FDA’s Center for Drug Evaluation and Research.” *Washington*
5 *Post*, August 5, 2001.

6 35. “A total of 36 deaths occurred during the [CLASS] study or during post study
7 follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group
8 Most deaths were cardiovascular in nature.” FDA CLASS Review, at 54. The increased number
9 of adverse cardiovascular events in the CELEBREX group was not surprising as they were also
10 revealed in the original New Drug Application (NDA) submitted for CELEBREX. “In the
11 original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as
12 compared to placebo treated patients. In the long term trial (Trial 024) that was included in the
13 NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any
14 does was cardiovascular.” FDA CLASS Review at 78.

15 36. Public Citizen, a public watchdog organization, reviewed the CLASS data in its
16 entirety. A complete review reveals the combined anginal adverse events were 1.4% in celecoxib
17 (CELEBREX) group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in
18 the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

19 37. The CLASS data proves that Pfizer knew that its first generation Cox-2 inhibitor,
20 CELEBREX, caused a disproportionately and statistically significantly high number of adverse
21 cardiovascular events before it was introduced to the market in January 1999. According to
22 Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the CV risk of
23 COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this
24 placebo-controlled trial of CELEBREX.

25 3. APC Trial

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1 38. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and
 2 safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the
 3 number of deaths from cardiovascular causes was significantly higher in the CELEBREX group
 4 when compared to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX
 5 400mg). Id. at 1075.

7 39. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and
 8 safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the
 9 number of deaths from cardiovascular causes was significantly higher in the CELEBREX group
 10 when compared to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX
 11 400mg). Id. at 1075.

13 40. The FDA Reported the APC data as follows¹:

15 In the National Cancer Institute's Adenoma Prevention with
 16 Celecoxib (APC) trial in patients at risk for recurrent colon polyps,
 17 a 2-3 fold increased risk of serious adverse CV events was seen for
 18 CELEBREX compared to placebo after a mean duration of
 19 treatment of 33 months. There appeared to be a dose response
 20 relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg
 twice daily and 3.4 CELEBREX 400 mg twice daily for the
 composite endpoint of death from CV causes, myocardial infarction
 (MI), or stroke.

21 41. The dosage noted in the study is important for two reasons: first, there appears to
 22 be an association between dosage and the increase in adverse cardiovascular events. See
 23 generally, at 1077. Second, most patients increase dosage. Pfizer knew patients were increasing
 24 their dosages as noted in CLASS: "Interestingly ... up to 70% of patients increased their dose for
 25 celecoxib." FDA CLASS Review at 74. Thus, Pfizer was aware of the dosage creep.

26 3. Other CELEBREX Trials

27 42. Several other CELEBREX trials also gave Defendants insight into the

28 ¹ April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm.

cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

43. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected “the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)”². According to Dr. Sidney Wolfe, “The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo.”³

4. Cox-2 Studies: VIGOR and APPROVE

44. Pfizer also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, Pfizer had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROV).

a. VIGOR

45. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

46. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

² Public Citizen, January 26, 2005, Dr. Sidney M. Wolfe.

³ Id.

1 47. The VIGOR study comprised the most definitive scientific evidence ever obtained
2 about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of
3 medical research. It was a safety study with endpoints set in advance. As Merck stated many
4 times, it was designed to provide definite proof of safety, convincing enough to silence the most
5 skeptical critics. In medical terms, the VIGOR results raised the question of whether selective
6 inhibition of Cox-2 was a monumental mistake from the start. While the NSAID risks to the GI
7 system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the
8 arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including
9 Defendants, were aware of these results.

10 **b. APPROVE**

11 48. Anxious to put safety questions surrounding Vioxx to rest, Merck designed
12 another large scale trial, Adenomatous Polyp Prevention (APPROVE), which was intended to test
13 the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular
14 safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of
15 the APPROVE data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and
16 "doubled the risk of MI (myocardial infarction a/k/a heart attack)⁴. *Public Citizen*, January 24,
17 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx,
18 Pfizer never paused to re-evaluating the CELEBREX data and studies.

19 49. The scientific data available during and after CELEBREX'S approval process
20 made clear to Defendants that their formulation of CELEBREX would cause a higher risk of
21 blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to
22 the need to do additional and adequate safety studies.

23 50. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of*
24 *Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing
25 to humans "... it is mandatory to conduct a trial specifically assessing cardiovascular risk and

26 ⁴ Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVE trial did
27 not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant
28 increase in risk of heart attack was evident in as little as 4 months time.

1 benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established
2 coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and
3 have the highest risk of further cardiovascular events.”

4 51. Dr. Topol was also the author on the study published in August 2001 in JAMA
5 (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who
6 used COX-2 inhibitors.

7 52. Based upon readily available scientific data, Defendants knew, or should have
8 known, that their pre-approval testing of CELEBREX did not adequately represent the cross-
9 section of individuals who were intended consumers and therefore, likely to take CELEBREX.
10 Therefore, Defendants’ testing and studies were grossly inadequate.

11 53. Had Defendants done adequate testing prior to approval and “market launch,”
12 rather than the extremely short duration studies done on the small size patient base that was
13 actually done the defendants’ scientific data would have revealed significant increases in
14 incidence of strokes and myocardial infarctions among the intended and targeted population of
15 CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed
16 serious side effects. Defendants should have taken appropriate measures to ensure that their
17 defectively designed product would not be placed in the stream of commerce and/or should have
18 provided full and proper warnings accurately and fully reflecting the scope and severity of
19 symptoms of those side effects should have been made.

20 54. In fact, post-market approval data did reveal increased risks of clotting, stroke and
21 myocardial infarction, but Defendants intentionally suppressed this information in order for them
22 to gain significant profits from continued CELEBREX sales.

23 55. Defendants’ failure to conduct adequate testing and/or additional testing prior to
24 “market launch” was based upon their desire to generate maximum financial gains for themselves
25 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

26 56. At the time Defendants manufactured, advertising, and distributed CELEBREX to
27 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding
28

1 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants
2 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but
3 instead would purchase other cheaper and safer NSAIDs.

4 **D. Facts Regarding Defendants' Marketing and Sale of CELEBREX**

5 57. Such an ineffective and unreasonably dangerous drug could only be widely
6 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the
7 Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and
8 misleading advertising, consumers, including the Plaintiff, would not have purchased
9 CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

10 58. On January 10, 2005 the FDA issued Pfizer a written reprimand for its
11 promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and
12 2 Celebrex] variously: omit material facts ... and make misleading safety, unsubstantiated
13 superiority, and unsubstantiated effectiveness claims." This was not the Defendants first offense
14 related to its Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting:
15 "DDMAC has reviewed these promotional pieces and has determined that they are false or
16 misleading because they contain unsubstantiated comparative claims, misrepresentations of
17 CELEBREX'S safety profile, and are lacking in fair balance." Ultimately, on April 8, 2005, the
18 New York Times reported the results of an FDA advisory panel: "The February advisory panel
19 voted overwhelmingly that the company should never again advertise the drug [CELEBREX]."

20 59. At all times relevant herein, Defendants engaged in a marketing campaign with the
21 intent that consumers would perceive CELEBREX as a safer and better drug than its other
22 NSAIDs and, therefore, purchase CELEBREX.

23 60. Defendants widely and successfully marketed CELEBREX throughout the United
24 States by, among other things, conducting promotional campaigns that misrepresented the
25 efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was
26 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.
27 Defendants made misrepresentations by means of media advertisements, and statements
28 contained in sales literature provided to Plaintiff's prescribing physicians.

1 61. Despite knowledge of the dangers presented by CELEBREX, Defendants and
2 Defendants' predecessors in interest, through their officers, directors and managing agents for the
3 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy
4 the known defects of Defendants' product, CELEBREX, and failed to warn the public, including
5 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,
6 CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with
7 the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants'
8 product, CELEBREX, knowing that persons would be exposed to serious potential danger, in
9 order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and
10 displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

11 62. In an elaborate and sophisticated manner, Defendants aggressively marketed
12 CELEBREX directly to consumers and medical professionals (including physicians and leading
13 medical scholars) in order to leverage pressure on third party payers, medical care organizations,
14 and large institutional buyers (e.g., hospitals) to include CELEBREX on their formularies. Faced
15 with the increased demand for the drug by consumers and health care professionals that resulted
16 from Defendants' successful advertising and marketing blitz, third party payors were compelled
17 to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted
18 third party payors, physicians, and consumers, and was designed to convince them of both the
19 therapeutic and economic value of CELEBREX.

20 63. Defendants represented that CELEBREX was similar to ibuprofen and naproxen
21 but was superior because it lacked any of the common gastrointestinal adverse side effects
22 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,
23 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with
24 long-term use. Defendants promoted CELEBREX as a safe and effective alternative that would
25 not have the same deleterious and painful impact on the gut, but that would be just as effective, if
26 not more so, for pain relief.

1 64. CELEBREX possessed dangerous and concealed or undisclosed side effects,
2 including the increased risk of serious cardiovascular events, such as heart attacks, unstable
3 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as
4 strokes. In addition, CELEBREX was no more effective than traditional and less expensive
5 NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and
6 gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

7 65. Defendants knew of these risks before the U.S. Food and Drug Administration (the
8 “FDA”) approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed,
9 omitted, and concealed these serious safety risks and denied inefficacy in its promotion,
10 advertising, marketing, and sale of CELEBREX. Defendants’ omission, suppression, and
11 concealment of this important information enabled CELEBREX to be sold to, and purchased, or
12 paid for by, the Consumers at a grossly inflated price.

13 66. Consequently, CELEBREX captured a large market share of anti-inflammatory
14 drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded \$2
15 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in
16 the same family of drugs.

17 67. Because Defendants engaged in a promotional and marketing campaign that
18 featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer
19 drug than other drugs in its class, while uniformly failing to disclose the health risks of
20 CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the
21 cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed
22 the truth about CELEBREX, Defendants would not and could not have reaped the billions of
23 dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission,
24 suppression, and obfuscation of the truth.

25 68. The Defendants intentionally, deliberately, knowingly, and actively concealed,
26 omitted, suppressed, and obfuscated important and material information regarding the risks,
27 dangers, defects, and disadvantages of CELEBREX from Plaintiff, the public, the medical
28

1 community, and the regulators. This concealment and omission was deliberate, knowing, active,
2 and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and
3 prevented Plaintiff from obtaining all the material information that would be important to their
4 decisions as reasonable persons to purchase, pay for, and/or use CELEBREX.

5 69. Defendants' systematic, active, knowing, deliberate, and uniform concealment,
6 omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use
7 CELEBREX; and caused Plaintiff's losses and damages as asserted herein.

8 70. Had Defendants done adequate testing prior to approval and "market launch," the
9 defendants' scientific data would have revealed significant increases in stroke and myocardial
10 infarction amongst the intended population of CELEBREX consumers. Adequate testing would
11 have shown that CELEBREX possessed serious side effects. Defendants should have taken
12 appropriate measures to ensure that their defectively designed product would not be placed in the
13 stream of commerce and/or should have provided full and proper warnings accurately and fully
14 reflecting the scope and severity of symptoms of those side effects should have been made.

15 71. In fact, post-market approval data did reveal increased risks of clotting, stroke and
16 myocardial infarction, but Defendants intentionally suppressed this information in order for them
17 to gain significant profits from continued CELEBREX sales.

18 72. Defendants' failure to conduct adequate testing and/or additional testing prior to
19 "market launch" was based upon their desire to generate maximum financial gains for themselves
20 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

21 73. At the time Defendants manufactured, advertising, and distributed CELEBREX to
22 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding
23 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants
24 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but
25 instead would purchase other cheaper and safer NSAID drugs.
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CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence

74. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

75. Defendants owed Plaintiffs a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling CELEBREX. This duty included the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects.

76. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical drug CELEBREX.

77. Defendants breached their duties by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of CELEBREX, including: failing to use due care in the preparation and development of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

a. failing to use due care in the design of CELEBREX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

b. failing to conduct adequate pre-clinical testing and research to determine the safety of CELEBREX;

c. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CELEBREX;

d. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the medical community, and the FDA;

1 e. failing to accompany CELEBREX with proper warnings regarding all possible
2 adverse side effects associated with the use of CELEBREX;

3
4 f. failing to use due care in the manufacture, inspection, and labeling of CELEBREX
5 to prevent the aforementioned risk of injuries to individuals who used CELEBREX;

6
7 g. failing to use due care in the promotion of CELEBREX to prevent the
8 aforementioned risk of injuries to individuals when the drugs were ingested;

9
10 h. failing to use due care in the sale and marketing of CELEBREX to prevent the
11 aforementioned risk of injuries to individuals when the drugs were ingested;

12 i. failing to use due care in the selling of CELEBREX to prevent the aforementioned
13 risk of injuries to individuals when the drugs were ingested;

14
15 j. failing to provide adequate and accurate training and information to the sales
16 representatives who sold CELEBREX;

17
18 k. failing to provide adequate and accurate training and information to healthcare
19 providers for the appropriate use of CELEBREX; and

20
21 l. being otherwise reckless, careless and/or negligent.

22 79. Despite the fact that Defendants knew or should have known that CELEBREX
23 caused unreasonable and dangerous side effects which many users would be unable to remedy by
24 any means, Defendants continued to promote and market CELEBREX to consumers, including
25 Plaintiffs, when safer and more effective methods of pain relief were available.
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1 80. Defendants were, or should have been, had they exercised reasonable care, in
2 possession of evidence demonstrating that CELEBREX caused serious side effects. Nevertheless,
3 they continued to market their products by providing false and misleading information with
4 regard to the safety and efficacy of CELEBREX.

5
6 81. Defendants knew or should have known that consumers such as Plaintiffs would
7 foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

8 82. As a direct and proximate consequence of Defendants' acts, omissions, and
9 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
10 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
11 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
12 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
13 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
14 preexisting conditions and activation of latent conditions, and other losses and damages.
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17 Plaintiffs also incurred direct medical losses and costs include care for hospitalization,
18 physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss
19 of wages.

20
21 83. Defendants' conduct was committed with knowing, conscious, wanton, willful,
22 and deliberate disregard for the value of human life and the rights and safety of consumers,
23 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
24 punish Defendants and deter them from similar conduct in the future.

25
26 84. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
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28

1 compensatory damages, and exemplary and punitive damages together with interest, the costs of
2 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

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4 **SECOND CLAIM FOR RELIEF**

5 **Strict Liability**

6 85. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
7 fully set forth herein and further allege as follows.

8 86. At all times relevant to this action, Defendants were suppliers of CELEBREX,
9 placing the drug into the stream of commerce. CELEBREX was expected to and did reach
10 Plaintiffs without substantial change in the condition in which it was manufactured and sold.

11 87. CELEBREX was unsafe for normal or reasonably anticipated use.

12 88. CELEBREX was defective in design or formulation because when it left the hands
13 of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an
14 ordinary consumer would expect. CELEBREX was also defective and unreasonably dangerous in
15 that the foreseeable risk of injuries from CELEBREX exceeded the benefits associated with the
16 design and/or formulation of the product.

17 89. Celebrex is unreasonably dangerous: a) in construction or composition; b) in
18 design; c) because an adequate warning about the product was not provided; d) because it does
19 not conform to an express warranty of the manufacturer about the product.

20 90. The characteristics of Celebrex that render it unreasonably dangerous under
21 existed at the time the product left the control of the manufacturer or resulted from a
22 reasonably anticipated alteration or modification of the product.

23 91. The CELEBREX manufactured and supplied by Defendants was also defective
24 due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate
25 reporting regarding the results of the clinical trials, testing and study. Defendants failed to
26 perform adequate testing before exposing Plaintiffs to the medication, testing which would have
27 shown that CELEBREX had the potential to cause serious side effects including strokes like that
28 which affected Plaintiffs.

92. The CELEBREX manufactured and supplied by Defendants was defective due to

1 inadequate post-marketing warnings or instructions because, after Defendants knew or should
2 have known of the risk of injuries from CELEBREX, they failed to provide adequate warnings to
3 the medical community and the consumers, to whom they were directly marketing and
4 advertising CELEBREX; and, further, it continued to affirmatively promote CELEBREX as safe
5 and effective.

6 93. CELEBREX was manufactured, distributed, tested, sold, marketed, advertised and
7 promoted defectively by Defendants, and as a direct and proximate cause of Defendants'
8 defective design of CELEBREX, Plaintiffs used CELEBREX rather than other safer and cheaper
9 NSAIDs. As a result, Plaintiffs suffered the personal injuries described above.

10 94. Information given by Defendants to the medical community and to the consumers
11 concerning the safety and efficacy of CELEBREX, especially the information contained in the
12 advertising and promotional materials, did not accurately reflect the potential side effects of
13 CELEBREX.

14 95. Had adequate warnings and instructions been provided, Plaintiffs would not have
15 taken CELEBREX as they did, and would not have been at risk of the harmful side effects
16 described herein.

17 96. Defendants acted with conscious and deliberate disregard of the foreseeable harm
18 caused by CELEBREX.

19 97. Plaintiffs could not, through the exercise of reasonable care, have discovered
20 CELEBREX's defects or perceived the dangers posed by the drug.

21 98. As a direct and proximate consequence of Defendants' acts, omissions, and
22 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
23 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
24 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
25 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
26 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
27 preexisting conditions and activation of latent conditions, and other losses and damages.
28 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

1 99. Defendants' conduct was committed with knowing, conscious, wanton, willful,
2 and deliberate disregard for the value of human life and the rights and safety of consumers,
3 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
4 punish Defendants and deter them from similar conduct in the future.

5 100. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
6 compensatory damages, and punitive and exemplary damages together with interest, the costs of
7 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

8 **THIRD CLAIM FOR RELIEF**

9 **Breach of Express Warranty**

10 101. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
11 fully set forth herein and further allege as follows.

12 102. Defendants expressly represented to Plaintiffs and other consumers and the
13 medical community that CELEBREX was safe and fit for its intended purposes, that it was of
14 merchantable quality, that it did not produce any dangerous side effects, particularly any
15 unwarned-of side effects, and that it was adequately tested.

16 103. These warranties came in the form of:

17 a. Defendants' public written and verbal assurances of the safety and efficacy of
18 CELEBREX;

19 b. Press releases, interviews and dissemination via the media of promotional
20 information, the sole purpose of which was to create an increased demand for CELEBREX,
21 which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to
22 the long-term ingestion of CELEBREX;

23 c. Verbal and written assurances made by Defendants regarding CELEBREX and
24 downplaying the risk of injuries associated with the drug;

25 d. False and misleading written information, supplied by Defendants, and published
26 in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing
27 CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

28 e. advertisements.

1 104. The documents referred to above were created by and at the direction of
2 Defendants.

3 105. Defendants knew or had reason to know that CELEBREX did not conform to these
4 express representations in that CELEBREX is neither as safe nor as effective as represented, and
5 that CELEBREX produces serious adverse side effects.

6 106. CELEBREX did not and does not conform to Defendants' express representations
7 because it is not safe, has numerous and serious side effects, including unwarned-of side effects,
8 and causes severe and permanent injuries.

9 107. Plaintiffs, other consumers, and the medical community relied upon Defendants'
10 express warranties.

11 108. As a direct and proximate consequence of Defendants' acts, omissions, and
12 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
13 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
14 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
15 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
16 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
17 preexisting conditions and activation of latent conditions, and other losses and damages.
18 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
19 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

20 109. Defendants' conduct was committed with knowing, conscious, wanton, willful,
21 and deliberate disregard for the value of human life and the rights and safety of consumers,
22 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to
23 punish Defendants and deter them from similar conduct in the future.

24 110. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
25 compensatory damages, and punitive and exemplary damages together with interest, the costs of
26 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

27 **FOURTH CLAIM FOR RELIEF**

28 **Breach of Implied Warranty**

111. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if

1 fully set forth herein and further allege as follows.

2 112. Defendants manufactured, distributed, advertised, promoted, and sold
3 CELEBREX.

4 113. At all relevant times, Defendants knew of the use for which CELEBREX was
5 intended and impliedly warranted the product to be of merchantable quality and safe and fit for
6 such use.

7 114. Defendants were aware that consumers, including Plaintiffs, would use
8 CELEBREX for treatment of pain and inflammation and for other purposes.

9 115. Plaintiffs and the medical community reasonably relied upon Defendants'
10 judgment and expertise to only sell them or allow them to prescribe CELEBREX only if it was
11 indeed of merchantable quality and safe and fit for its intended use. Consumers, including
12 Plaintiffs, and the medical community, reasonably relied upon Defendants' implied warranty for
13 CELEBREX.

14 116. CELEBREX reached consumers, including Plaintiffs, without substantial change
15 in the condition in which it was manufactured and sold by Defendants.

16 117. Defendants breached their implied warranty to consumers, including Plaintiffs;
17 CELEBREX was not of merchantable quality or safe and fit for its intended use.

18 118. As a direct and proximate consequence of Defendants' acts, omissions, and
19 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
20 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
21 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
22 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
23 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
24 preexisting conditions and activation of latent conditions, and other losses and damages.
25 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
26 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

27 119. Defendants' conduct was committed with knowing, conscious, wanton, willful,
28 and deliberate disregard for the value of human life and the rights and safety of consumers,
including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to

1 punish Defendants and deter them from similar conduct in the future.

2 120. WHEREFORE, Plaintiffs demand judgment against Defendants and seek
3 compensatory damages and punitive and exemplary damages together with interest, the costs of
4 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

5 **FIFTH CLAIM FOR RELIEF**

6 **Fraudulent Misrepresentation & Concealment**

7 121. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if
8 fully set forth herein and further allege as follows.

9 122. Defendants' superior knowledge and expertise, their relationship of trust and
10 confidence with doctors and the public, their specific knowledge regarding the risks and dangers
11 of CELEBREX, and their intentional dissemination of promotional and marketing information
12 about CELEBREX for the purpose of maximizing its sales, each gave rise to the affirmative duty
13 to meaningfully disclose and provide all material information about CELEBREX's risks and
14 harms to doctors and consumers.

15 123. Defendants made fraudulent affirmative misrepresentations with respect to
16 CELEBREX in the following particulars:

17 a. Defendants represented through their labeling, advertising, marketing materials,
18 detail persons, seminar presentations, publications, notice letters, and regulatory submissions that
19 CELEBREX had been tested and found to be safe and effective for the treatment of pain and
20 inflammation; and

21 b. Defendants represented that CELEBREX was safer than other alternative
22 medications.

23 124. Defendants made affirmative misrepresentations; and fraudulently, intentionally
24 and/or recklessly concealed material adverse information regarding the safety and effectiveness of
25 CELEBREX.

26 125. Defendants made these misrepresentations and actively concealed adverse
27 information at a time when Defendants knew or had reason to know that CELEBREX had defects
28 and was unreasonably dangerous and was not what Defendants had represented to the medical
community, the FDA and the consuming public, including Plaintiffs.

1 126. Defendants omitted, suppressed and/or concealed material facts concerning the
2 dangers and risk of injuries associated with the use of CELEBREX including, but not limited to,
3 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'
4 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the
5 serious nature of the risks associated with the use of CELEBREX in order to increase its sales.

6 127. The representations and concealment were undertaken by Defendants with an
7 intent that doctors and patients, including Plaintiffs, rely upon them.

8 128. Defendants' representations and concealments were undertaken with the intent of
9 defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and
10 encourage the sale of CELEBREX.

11 129. Defendants' fraudulent representations evinced their callous, reckless, willful, and
12 depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

13 130. Plaintiffs' physician and Plaintiffs relied on and were induced by Defendants'
14 misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX in
15 selecting CELEBREX treatment.

16 131. Plaintiffs and the treating medical community did not know that the
17 representations were false and were justified in relying upon Defendants' representations.

18 132. Had Plaintiffs been aware of the increased risk of side effects associated with
19 CELEBREX and the relative efficacy of CELEBREX compared with other readily available
20 medications, Plaintiffs would not have taken CELEBREX as he did.

21 133. As a direct and proximate consequence of Defendants' acts, omissions, and
22 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.
23 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred
24 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will
25 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the
26 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of
27 preexisting conditions and activation of latent conditions, and other losses and damages.
28 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician
care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

134. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

135. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CLAIM FOR RELIEF

Unjust Enrichment

136. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

137. At all times relevant to this action, Defendants were the manufacturers, sellers, and/or suppliers of CELEBREX.

138. Plaintiffs paid for CELEBREX for the purpose of managing their pain safely and effectively.

139. Defendants have accepted payment from Plaintiffs for the purchase of CELEBREX.

140. Plaintiffs did not receive the safe and effective pharmaceutical product for which she paid.

141. It is inequitable and unjust for Defendants to retain this money because Plaintiffs did not in fact receive the product Defendant represented CELEBREX to be.

142. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

1. General damages in excess of the jurisdictional amount of this Court;
2. Consequential damages;
3. Disgorgement of profits;

4. Restitution;
5. Damages for loss of consortium, care, comfort, society and companionship in an amount within the jurisdiction of this Court and according to proof;
6. Punitive and exemplary damages;
7. Pre-judgment and post-judgment interest as provided by law;
8. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court costs of these causes, and those costs available under the law, as well as expert fees and attorneys' fees and expenses, and costs of this action; and
9. Such other and further relief as the Court deems just and proper.

Dated: December 11, 2007

Respectively submitted,

By: Navan Ward Jr
Andy D. Birchfield, Jr. (AL State Bar No. BIR006)
Email: andy.birchfield@beasleyallen.com
Navan Ward, Jr. (AL State Bar No. WAR062)
Email: navan.ward@beasleyallen.com
BEASLEY, ALLEN, CROW, METHVIN,
PORTIS & MILES, P.C.
Post Office Box 4160
Montgomery, Alabama 36103-4160
(334) 269-2343 telephone
(334) 954-7555 facsimile
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims so triable in this action.

1 Dated: December 11, 2007 Respectfully submitted,

2
3
4 By: Navan Ward
5 Andy D. Birchfield, Jr. (BIR006)
6 Navan Ward, Jr. (WAR062)
7 BEASLEY, ALLEN, CROW, METHVIN,
8 PORTIS & MILES, P.C.
9 P. O. Box 4160
10 Montgomery, Alabama 36103-4160
11 Telephone: (334) 269-2343
12 Facsimile: (334) 954-7555

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ATTORNEYS FOR PLAINTIFFS